1636

Dkt. 55424-Z/JPW/ALB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#11

Applicant	:	Ann Marie Schmidt, et al.	
U.S. Serial No.:		09/851,071	Examiner: S. Kaushal
Filed	:	May 8, 2001	Group Art Unit: 1636
For	:	A METHOD FOR INHIBITING TUMOR INVASION OR SPREADING IN A SUBJECT	

1185 Avenue of the Americas
New York, New York 10036
January 17, 2003

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

COMMUNICATION IN RESPONSE TO DECEMBER 17, 2002 OFFICE ACTION

This Communication is submitted in response to a December 17, 2002 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A Response to the December 17, 2002 Office Action is due January 17, 2003. Accordingly, this Communication is being timely filed.

Restriction Requirement Under 35 U.S.C. §121

The Examiner required restriction to one of the following inventions under 35 U.S.C. §121:

I. Claims 17-21, 37-38 and 22-25, allegedly drawn to a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent is an

antibody, classified in class 424, subclass 130.1.

II. Claims 17-21, 37-38 and 26-32, allegedly drawn to a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent is a peptide classified is class 512, subclass 2.

III. Claims 17-21, 37-38 and 33-35, allegedly drawn to a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent inhibits an interaction between tumor cell and extracellular matrix molecule classified in class 435, subclass 375.

IV. Claims 17-21 and 36-38, allegedly drawn to a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent inhibits the binding of RAGE to amphoterin, classified in class 435, subclass 375.

The Examiner alleged that Claim 21 is generic to a plurality of disclosed patentably distinct species comprising: a peptide, a nucleic acid, a synthetic organic compound, an inorganic molecule, a carbohydrate, a lipid, an antibody or a small molecule. The Examiner alleged that the applicant is required under 35 U.S.C. §121 to elect a single disclosed species, even though this requirement is traversed.

The Examiner stated that should applicant traverse on the grounds that the alleged species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under §35 U.S.C. 103(a) of the other invention.

The Examiner alleged that the inventions are distinct, each from the other because of the following reasons:

The Examiner alleged that inventions I and II are distinct. The Examiner stated that inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). The Examiner alleged that in the instant case, invention I is drawn to a method of inhibiting tumor invasion by administering an antibody, whereas invention II is drawn to a method of inhibiting tumor invasion by administering a polypeptide respectively. The Examiner alleged that these methods have different modes of operation and effects becasue polypeptides and antibodies are structurally and functionally distinct compounds. Thus, the Examiner alleged that these inventions are distinct and are of separate use.

The Examiner alleged that inventions III and IV are distinct. The Examiner alleged that inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). The Examiner

alleged that in the instant case, inventions III and IV are drawn to two distinct methods of evaluating the ability of an agent. The Examiner alleged that invention III is drawn to a method of screening agents that inhibit the interaction between a tumor cell and an extracellular matrix molecule, whereas invention IV is drawn to a method of screening agents that inhibit the binding of RAGE to amphoterin. Thus, the Examiner alleged that these inventions are distinct and are of separate use.

In addition, the Examiner alleged that inventions of groups I and II are distinct from inventions of group III and IV since each have different modes of operation, functions or effects. The Examiner alleged that the invention of group I and II require the use of a polypeptide or antibody to inhibit tumor invasion, whereas the invention of group III and IV require identification of agents that specifically inhibit interaction between tumor cell/extracellular matrix and RAGE/amphoterin respectively. Thus. The Examiner alleged that these inventions are distinct and are of separate use.

The Examiner alleged that because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications, restriction for examination purposes as indicated is proper.

The Examiner advised applicant that in order for the reply to this requirement to be complete, it must include an election of the invention to be examined even though the requirement is traversed (37 C.F.R. §1.143).

The Examiner reminded the applicant that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b), if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. The Examiner recited that any amendment of inventorship must be accompanied by a request under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

In response to this restriction requirement, applicant's undersigned attorney, on behalf of applicant, hereby elects, with traverse, to prosecute the invention of Examiner's Group III, i.e. Claims 17-21, 33-35 and 37-38, allegedly drawn to a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent inhibits an interaction between a tumor cell and an extracellular matrix molecule classified in class 435, subclass 375.

Applicant notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction of Examiner's Group III from Examiner's Groups I-II and IV be withdrawn in view of the fact that the claims of Examiner's Group III are not independent of Examiner's Groups I-II and IV. Applicant maintains that the claims of Examiner's Group III and Examiner's Groups I-II and IV do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect." The claims of Examiner's Group III, allegedly drawn to a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent inhibits an interaction between a tumor cell and an extracellular matrix molecule, are related to the claims of Examiner's Groups I-II and IV, in that the claims in all groups are directly related to a method for determining whether an agent inhibits the binding of receptor of advanced glycation enproduct (RAGE) on a tumor cell with a ligand, thereby inhibiting tumor cell invasion.

The claims of Examiner's Group III, allegedly drawn to a method a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent inhibits an interaction between a tumor cell and an extracellular matrix molecule, are related to Examiner's groups IV, II and I, because of the reliance of all identified claims on the ability of an agent to inhibit RAGE/ligand binding as part of their design, operation, and effect. The specification recites that "in our studies, we tested the hypothesis that blockade of tumor cell RAGE would interfere with the ability of tumors to compromise the integrity of their local environment, at least in part by disruption of the RAGE (cellular) - amphoterin (matrix) interaction." See page 17, lines 36-37 and page 18, lines 1-3. Therefore, Examiner's Group III, allegedly drawn to a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent inhibits an interaction between a tumor cell and an extracellular matrix

molecule, Examiner's Group IV, allegedly drawn to a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent inhibits the binding of RAGE to amphoterin, and Examiner's Groups I and II, allegedly drawn to a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent is an antibody or a peptide, respectively, utilize the ability of an agent to inhibit RAGE/ligand interaction as part of their design, operation, and effect. Accordingly, applicants request that the Examiner examine Groups I-IV on the merits.

Applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Examiner's Group III, claims 17-21,33-35 and 37-38 allegedly drawn to a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent inhibits an interaction between a tumor cell and an extracellular matrix molecule, will reveal whether any prior art exists as to a method for identifying a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent inhibits the binding of RAGE to amphoterin (Group IV), a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent is a peptide (Group II), and a method of evaluating the ability of an agent to inhibit tumor invasion, wherein the agent is an antibody (Group I). Since there is no burden on the Examiner to examine Groups I-IV in the subject application, the Examiner must examine the entire application on the merits.

Applicant maintains that claims 17-38 define a single inventive

concept. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement and examine claims 17-38 on the merits.

In addition, in response to this restriction requirement, applicant's undersigned attorney, on behalf of applicant, hereby elects, with traverse, the following alleged species of claim 21:

1) a small molecule.

In addition, applicants request that upon the allowance of a generic claim, consideration of claims to additional species which are written in dependent form be considered.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invite the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

1/17/03

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